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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,994	07/14/2003	Scott Cunningham	2848	5963
50855	7590	05/17/2006	EXAMINER	
UNITED STATES SURGICAL, A DIVISION OF TYCO HEALTHCARE GROUP LP 195 MCDERMOTT ROAD NORTH HAVEN, CT 06473				YABUT, DIANE D
		ART UNIT		PAPER NUMBER
		3734		

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,994	CUNNINGHAM ET AL.	
	Examiner	Art Unit	
	Diane Yabut	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 July 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 14 July 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/16/2003</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 16 October 2003 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

2. The abstract of the disclosure is objected to because it exceeds 150 words. Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities: On page 1, line 8, it reads "multifaceted" and should be changed to --multifaceted--. On page 5, line 19, it reads "corresponding to a y-dimension" and should rather be --corresponding to a z-dimension-- since in line 15, the transverse axes "z" corresponds to the width dimension of the needle body.

Appropriate correction is required.

Drawings

4. The drawings are objected to because the "needle head 22" is mentioned in the specification on page 6, lines 16 and 18, as well as on page 7, lines 5,9,16,19, and 22, but is not shown in any of the Figures. Also, the drawings and the reference numbers/letters should be enlarged – there should be one to two Figures per page for clarity. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

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replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 1,02 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-4,10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Guido** (U.S. Patent No. 5,342,397) in view of **Smith** (U.S. Patent No. 4,513,747).

Claim 1: Guido discloses an elongated needle body 10, that defines a longitudinal y-axis and x and z axes transverse to the y-axis, and a central shaft 18 having a first end

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22 and a second needled end **12** (Figure 2). The needled end **12** has lower and upper opposed surfaces and side surfaces **70** (Figure 9).

Guido discloses the claimed device except for the side surfaces extending to a pointed tip and the lower surface extending to a cutting edge defined at the intersection of the side surfaces and proximal of the pointed tip and extending in oblique relation relative to the longitudinal axis.

Smith teaches side surfaces **31** and **32** that extend to a pointed tip **60** and a lower surface of body portion **41** that extends to a cutting edge **21** defined at the intersection of the side surfaces **31** and **32** and proximal of the pointed tip, and also extends in oblique relation relative to the longitudinal axis of the upper surface **33**.

Smith teaches that surgical needles are required to be as sharp as possible at the tip in order to function properly (col. 1, lines 10-12). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the side surfaces extending to a pointed tip, as taught by Smith, to the device of Guido, in order to be sharp as required for proper function, which is known in the art since sharper needles require less force and therefore less tissue trauma.

Smith also teaches that the cutting edge that extends in oblique relation relative to the longitudinal axis serves as an angle of slope which determines the rate at which tissues are cut, and therefore may be altered depending on the application and the tissue to be cut (col. 3, lines 32-41). It would have been obvious to provide side surfaces extending to a pointed tip and the lower surface extending to a cutting edge defined at the intersection of the side surfaces, which extends in oblique relation relative

to the longitudinal axis, as taught by Smith, in order to provide an angle of slope that determines the rate at which tissues are cut.

Claim 2: Guido discloses upper and lower surfaces 70 that are substantially planar (Figures 9-11).

Claim 3: Guido discloses a first transverse cross-sectional dimension adjacent to the central shaft that defines a general trapezoidal configuration (Figure 11).

Claim 4: Guido lacks a second transverse cross-sectional dimension adjacent the pointed tip defining a general triangular configuration. However, Smith discloses a cross-sectional dimension adjacent to the pointed tip 60 that has a general triangular configuration (Figure 4). Smith teaches that this configuration allows for a long cutting action and a decrease in the likelihood of deformation of the tip (col. 4, lines 4-6). It would have been obvious to one of ordinary skill in the art to use the teaching of Smith in the needle of Guido in order to provide long cutting action and to decrease the chance of the needle tip bending.

Claim 10: Guido discloses a needle body that is curved along the longitudinal axis (Figure 2).

Claim 12: Guido lacks a linear cutting edge intersecting the upper planar surface at an angle ranging from about 15 to about 30 degrees relative to the longitudinal axis. Smith discloses an angle of slope d between the cutting edge 21 and upper surface 33 that ranges from about 15 to 30 degrees relative to the longitudinal axis (Figure 3, col. 5, lines 4-9). Smith teaches that this range of angles provides ease of passage of the need through the tissue (col. 3, lines 36-38). It would have been obvious to modify

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Guido with the linear cutting edge intersecting the upper planar surface at an angle ranging from 15 to about 30 degrees in order for the needle to easily pass through tissue.

7. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Guido** (U.S. Patent No. 5,342,397) and **Smith** (U.S. Patent No. 4,513,747) as applied to Claim 4 above, and further in view of **Cunningham** (U.S. Pub. No. 20040106948).

Claims 5-7: Guido and Smith lack a first cross-sectional dimension defining a dimension along the z-axes corresponding to a first width of the needle end, which is at least equal to a corresponding shaft width of the central shaft, greater than a corresponding shaft width of the central shaft, and not less than about 1.5 times the shaft width.

Cunningham teaches a surgical needle that has a cross-sectional dimension that defines a dimension along the z-axes corresponding to a first width **W1** of the needle end, which is at least equal to the corresponding shaft width **W** of the central shaft, is greater than the corresponding shaft width **W**, and is not less than about 1.5 times the shaft width **W** (Figure 3, page 2, paragraph 30). Cunningham teaches that the wider portion **W1** at the needle end, after passing through tissue, provides a large opening that reduces the drag force and permits the shaft width **W** to easily pass through the tissue (pages 2-3, paragraph 34). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the dimension of a first width of the needle end being at least equal to a corresponding shaft width of the central shaft, greater than a corresponding shaft width of the central shaft, and not less than about 1.5 times the

shaft width, as taught by Cunningham, to the combined device of Guido and Smith, in order to provide a large cut through the tissue that reduces drag force and permits the rest of the needle to pass through easily.

8. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Guido** (U.S. Patent No. 5,342,397), **Smith** (U.S. Patent No. 4,513,747), and **Cunningham** (U.S. Pub. No. 20040106948), as applied to Claim 6 above, and further in view of **Naslund** (U.S. Patent No. 4,133,339).

Claims 8-9: Guido, Smith, and Cunningham lack a first cross-sectional dimension along an x-axis corresponding to a first height of the needle end, the first height being less than a corresponding shaft height of the central shaft, and not greater than about 0.5 times the shaft height.

Naslund teaches a needle capable of holding sutures that has a thickness ("first height") around a first portion 303, which is perpendicular to the width (col. 3, lines 27-29), that is less than a corresponding shaft portion 307 and not greater than about 0.5 times the shaft thickness. Naslund teaches that the diminished thickness allows for a corresponding increase in the thickness, and therefore an increase in rigidity of the needle (col. 2, lines 17-21). It would have been obvious to modify Guido, Smith, and Cunningham with the thickness dimension less than a corresponding shaft portion and not greater than about 0.5 times the shaft thickness, as taught by Naslund, because it allows an increase in the thickness of the needle and adds to the rigidity of the needle.

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9. Claim 11 rejected under 35 U.S.C. 103(a) as being unpatentable over **Guido** (U.S. Patent No. **5,342,397**), **Smith** (U.S. Patent No. **4,513,747**), as applied to Claim 10 above, and further in view of **McGregor et al.** (U.S. Patent No. **4,524,771**).

Claim 11: Guido and Smith disclose the claimed device except for the elongated needle shaft defining an angle of curvature ranging from about 80 to about 180 degrees.

McGregor et al. discloses an elongated needle shaft **25** with an angle of curvature within the range of about 80 to about 180 degrees. McGregor et al. teaches that the curve in the needle is helpful in placing the suture by allowing the surgeon to grasp the body of the needle near its center and allows the suture to be placed at a desired depth by a controlled emergence of the needle from the tissue (col. 1, lines 9-24).

It would have been obvious to one of ordinary skill in the art at the time of invention to provide an angle of curvature ranging from about 80 to about 180 degrees to the elongated needle shaft, as taught by McGregor et al., to the combined device of Guido and Smith, in order to facilitate placing the suture in the tissue to be closed at a desired depth.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: **Dabir et al.** (U.S. Patent No. **5,891,164**) discloses a suturing needle with an arcuate shape; **Wong et al.** (U.S. Patent No. **4,932,961**) discloses a surgical needle with a tapered end.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DY



MICHAEL J. HAYES
PRIMARY EXAMINER